IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: U.S. Patent Re. 36,755 (Reissue of U.S. Patent No. 5,712,155)

Issued: June 27, 2000 (Issue date of original patent: January 27, 1998)

Inventor: Smith, Craig A., Seattle Washington
Goodwin, Raymond G., Seattle, Washington
Beckmann, M. Patricia, Poulsbo, Washington

Assignee: Immunex Corporation, Seattle, Washington

For: DNA encoding tumor necrosis factor –alpha and –beta receptors

February 19, 2003

Commissioner of Patents
Box Patent Extension
Washington, D.C. 20231
Attn: Karin Ferriter

SECOND SUPPLEMENT TO APPLICATION FOR EXTENSION OF PATENT TERM BASED ON REGULATORY REVIEW OF A NEW DRUG APPLICATION AS PROVIDED UNDER 35 U.S.C. § 156(D)(1)

Dear Ms. Ferriter:

An Application for Extension of Patent Term based on Regulatory Review of a New Drug Application was filed for U.S. Patent No. 5,712,155 (now Re. 36,755) on December 22, 1998. A supplement to the original application was filed on August 31, 2000 following grant of the reissue patent (Re. 36,755).

This paper is submitted to further supplement the application in light of the calculation of the regulatory review period by the U.S. Food and Drug Administration (FDA) for ENBREL®.

After reviewing the calculation of the FDA, Applicants request an extension of **229 days** to the existing patent term, resulting in an expiration date for U.S. Patent Re. 36,755 of **October 22, 2012**, for reasons discussed below.

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Original Extension Calculations

The original application requested an extension of the patent term by 240 days, or, alternatively, 231 days. Calculation of those extensions relied upon the following dates:

Investigational New Drug (IND) effective date:	June 26, 1992
Patent Issue Date	January 27, 1998
Biological License Application (BLA) dates:	
Initial BLA CMC Section submission:	March 9, 1998
BLA Clinical Section submission (final submission to complete BLA)	May 7, 1998
Approval for the use of ENBREL®:	November 2, 1998

The 240 day extension initially requested was based on the approval phase beginning on March 9, 1998, the date the Chemistry, Manufacturing and Controls (CMC) Section was submitted to the FDA. The alternative 231 day extension initially requested was based on the approval phase beginning on May 7, 1998, the date the Clinical Section was submitted to the FDA. Applicants now amend those calculations in light of the dates confirmed by the FDA.

Applicable FDA Regulations

The FDA has asserted May 8, 1998 (one day after Applicants' submission of the Clinical Section) as the date of initial submission of the BLA. This date apparently reflects FDA regulations 21 C.F.R. § 60.22 (f) and 601.2.

Rule 60.22(f) states that "[f]or purposes of determining the regulatory review period for any product, ... a petition is *initially submitted* on the date it contains sufficient information to allow FDA to commence review of the application." (emphasis added). The CMC Section submitted on March 9, 1998 was the first of three sections to be submitted to the FDA. Under Rule 60.22(f), the BLA was not considered "initially submitted" until all parts, including the final Clinical Section, were submitted. The initial 240 day extension request was based on the March 9, 1998 submission of the CMC Section only.

Rule 601.2 states that "[a]n application for a biologics license shall not be considered as filed until all pertinent information and data have been *received* from the manufacturer." (emphasis added). Once again, the BLA was not considered final until all pertinent sections had been submitted. Applicants originally asserted May 7, 1998, the mailing date of the Clinical Section of the BLA, as the alternative date for submission of the BLA. Based on a May 7, 1998 date, Applicants initially provided an alternative patent term extension request of 231 days. Calculations using the May 8, 1998 BLA receipt date, confirmed by the FDA, results in a two day adjustment to the patent term extension, as explained below.

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Applicants acknowledge the May 8, 1998 BLA initial submission date confirmed by the FDA. The requested extension of the patent term is recalculated accordingly.

Amended Extension Calculations

Applicants' amended calculation of 229 days relies on the following dates:

Investigational New Drug (IND) effective date:	June 26, 1992
Patent Issue Date	January 27, 1998
Date BLA initially submitted: (final submission to complete BLA)	May 8, 1998
Date of approval for the use of ENBREL®:	November 2, 1998

For purposes of this calculation, the pertinent portion of the regulatory review phase totals 280 days including:

1. A testing phase of 101 days (from the patent issue date to the date the BLA was initially submitted); and

2. An approval phase of 179 days (from the date the BLA was initially submitted to the date of approval for the use of Enbrel).

Pursuant to 35 U.S.C. § 156 and 37 C.F.R. § 1.775 the proper extension of the patent term includes ½ the number of days in the testing phase and the full number of days in the approval phase:

½ Testing phase = ½ (101) = **50** ("half-days will be ignored" 37 C.F.R. 1.775(d)(1)(iii))

½ Testing phase + Approval phase = 50 + 179 = **229 days total**

Accordingly, Applicants respectfully request that the expiration of U.S. Patent Re. 36,755 be extended **229 days** beyond the current expiration of March 7, 2012 such that it will expire on **October 22, 2012.**

Applicants respectfully request that the Patent and Trademark Office calculate and confirm that this is the proper length of the patent term extension.

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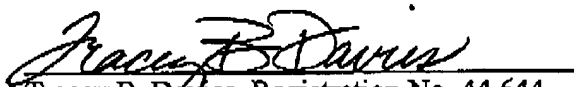
It is believed that no fee is due related to submission of this paper. If a fee is warranted, the Commissioner is hereby authorized to deduct said fee from deposit account 22-0365/IMM200/58000.

Respectfully submitted,

Immunex Corporation

By: 

Tracey B. Davies, Registration No. 44,644
Vinson & Elkins L.L.P.
2300 First City Tower
1001 Fannin
Houston, Texas 77002-6760
Telephone: (512) 542-8619
Facsimile: (512) 236-3215
Email: tdavies@velaw.com

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Vinson&Elkins V&E
ATTORNEYS AT LAW

VINSON & ELKINS L.L.P.
THE TERRACE 7
2801 VIA FORTUNA, SUITE 100
AUSTIN, TEXAS 78746
TELEPHONE (512) 542-8400
FAX (512) 542-8612
www.velaw.com

Tracey B. Davies
Direct Dial (512) 542-8619
Direct Fax (512) 236-3215
tdavies@velaw.com

February 13, 2003

Box: Patent Ext.
Commissioners for Patents
Washington, DC 20231

Re: Application for Extension of Patent Term, Patent No.: 5,713,155,
Issued: January 27, 1998; "DNA Encoding Tumor Necrosis Factor - Alpha and Beta Receptors," Smith et al.
Assignee: Immunex Corporation; Attorney Dkt: IMM200/58000/4-001EX

Dear Sir or Madam:

Applicants request that all correspondence and communications regarding the above-referenced patent term extension application be directed to:

Tracey B. Davies
Vinson & Elkins, L.L.P.
2300 First City Tower
1001 Fannin St.
Houston, Texas 77002-6760
(512) 542-8619 – telephone
(512) 236-3215 – fax

For your reference, a copy of the power of attorney filed with this patent term extension application is attached hereto.

If you have any questions, please contact the undersigned attorney at the number indicated above. Thank you for your time and attention to this matter.

Respectfully submitted,

Tracey B. Davies
Reg. No. 44,644

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cc: Karin Ferriter, USPTO, via facsimile

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In re:	US Patent No. RE 36,755
Issued:	June 27, 2000
Inventors:	Smith, Craig A., Seattle, Washington Goodwin, Raymond G., Seattle, Washington Beckmann, M. Patricia, Poulsbo, Washington
Assignee:	Immunex Corporation, Seattle, Washington
For:	DNA Encoding Tumor Necrosis Factor- alpha and - beta receptors

POWER OF ATTORNEY AND GENERAL AUTHORITY FROM AGENT OF ASSIGNEE

Commissioner for Patents
Washington, D.C. 20231

Sir:

Immunex Corporation hereby certifies that it is the assignee of the entire right, title and interest in the patent, and reissue application for patent.

The undersigned (whose title is supplied below) is empowered to act on behalf of the agent of said assignee.

The undersigned has reviewed all of the documents in the chain of title of the patent identified above and, to the best of undersigned's knowledge and belief, title is in the assignee identified above.

The agent of said assignee hereby appoints Willem G. Schuurman (Reg. No. 29,998); Gregory L. Porter (Reg. No. 40,131); Andrew G. DiNovo (Reg. No. 40,115), Minh-Hien Nguyen (Reg. No. 37,294); Adam V. Floyd (Reg. No. 39,192); Timothy S. Corder (Reg. No. 38,414); Brian K. Buss (Reg. No. 42,375); Tracey B. Davies (Reg. No. 44,644); Stephen J. Moloney (Reg. No. 44,947); David B. Weaver (Reg. No. 43,244) as its attorneys or agents with full power of substitution and revocation to transact all business in the Patent and Trademark Office in connection with the above-identified patent, including, but not limited to, filing for patent term extensions under 35 U.S.C. § 156. The agent of said assignee requests that all correspondence and telephone communications be directed to the following person at the mailing address and telephone number hereafter given:

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Tracey B. Davies
VINSON & ELKINS L.L.P.
2300 First City Tower
1001 Fannin Street
Houston, Texas 77002-6760
(512) 495-8619

The undersigned hereby declares that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the patent.

ASSIGNEE:

IMMUNEX CORPORATION

By: Mark Kirschner

Name: Michael Kirschner

Title: Vice President, MKF Intellectual Property

Date: August 25, 2000